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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,283	07/15/2005	Hans-Ulrich Petereit	273014US0PCT	5271

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EXAMINER	
SASAN, ARADHANA	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
05/01/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/542,283	PETEREIT ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *1-4, 8-9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-7,10 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/15/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II (claims 5-7, 10 and 11 in the reply filed on 3/12/08 is acknowledged. The traversal is on the ground(s) that the methacrylic acid copolymers taught in Examples 1 and 3 in the prior art reference, US 5,158,777 ('777) are EUDRAGIT L and EUDRAGIT RS, which contain quaternary ammonium groups and not tertiary amino groups as required by Applicant's claims. This is not found persuasive because the methacrylic acid copolymers taught in '777 render the instant methacrylic acid copolymers obvious, thereby breaking unity.

2. Claims 5-7 and 10-11 are included in the prosecution.

Priority

3. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on 7/15/05 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement.

See attached copy of PTO-1449.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 5-7 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petereit et al. (US 2003/0064036) in view of Bourns et al. (US 5,529,800).

The claimed invention is an active ingredient-containing powder with an average particle size of 200 μm or less, comprising (a) an anionic active pharmaceutical ingredient which is in the form of a solid solution and is incorporated into (b) a copolymer which consists of free-radical polymerized C_1 to C_4 esters of acrylic or methacrylic acid and further (meth)acrylate monomers which have functional tertiary amino groups, and (c) 5 to 50% by weight, based on (b), of a C_{12} to C_{22} carboxylic acid, (d) with the proviso that less than 3% by weight, based on the copolymer, or no emulsifier having an HLB of at least 14 is present.

Petereit teaches component (a) which is a copolymer that "consists essentially or entirely of free-radical-polymerized C_1 to C_4 esters of acrylic or methacrylic acid and further (meth)acrylate monomers which contain functional tertiary ammonium groups" (Page 1, [0014]). Petereit teaches component (b) which are emulsifiers with HLBs of at least 14, for example, sodium laurylsulphate and sodium cetylstearylsulphate, sucrose stearate and polysorbate 80, that are present in amounts of 1-15% by weight, based on component (a) (Page 2, [0026]). The reference also discloses component (c) which is 5

to 50% by weight (based on the component (a)) of a C_{12} to C_{18} monocarboxylic acid for example lauric acid, myristic acid, palmitic acid and stearic acid (Page 2, [0030] and [0032]). The process of producing a pharmaceutical formulation is disclosed where "the components (a), (b) and (c) are blended with one another at ambient or elevated temperature with or without addition of water and if desired of a pharmaceutical active compound and the further customary additives and the coating and binding agent is prepared by melting, casting, spreading, spraying or granulating" (Page 3, [0049]). Processes including direct compression, extrusion and binding of powders to active-compound-containing particles are disclosed (Page 3, [0056]). "The formulation … can be applied by granulating , … as a melt or in aqueous suspension" (Page 4, [0073]). Active ingredients such as analgesics and antirheumatics, including ibuprofen are disclosed (Page 6, [0094] – [0095]). A dispersion of a copolymer of methyl methacrylate, butyl methacrylate and dimethylaminoethyl methacrylate in the ratio 25:25:50 with an average particle size of 15 μm (EUDRAGIT® E PO) and a copolymer of methyl methacrylate, butyl methacrylate and dimethylaminoethyl methacrylate in the ratio 25:25:50 (EUDRAGIT® E 100) are disclosed (Page 6, 0109] and [0113]). Customary additives such as release agents, pigments, stabilizers, antioxidants, pore formers, penetration promoters, lustre agents, aromatic substances or flavourings are disclosed (Page 2, [0036]).

Petereit does not expressly teach that not more than 3% by weight, based on the copolymer, of emulsifiers having an HLB of at least 14 may be present.

Bourns teaches (frosting) formulations that use emulsifier systems including aerating emulsifiers such as Polysorbate 80 (Col. 8, lines 9-19). "Since at higher levels an objectionable taste can develop, the concentration of Polysorbate 80 should be 0.01 to 0.1% of the frosting" (Col. 8, lines 20-22).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to blend together a copolymer of free-radical-polymerized C_1 to C_4 esters of acrylic or methacrylic acid and further (meth)acrylate monomers which contain functional tertiary ammonium groups, 5 to 50% by weight (based on the component (a)) of a C_{12} to C_{18} monocarboxylic acid, a pharmaceutical active and customary additives, as taught by Petereit, reduce the emulsifier level because of the objectionable taste, as suggested by Bourns, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Bourns teaches that higher levels of emulsifiers lead to objectionable taste. Therefore, one with ordinary skill in the art would reduce the level of emulsifier in the process of producing the pharmaceutical formulation.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claims 5 and 10, the active ingredient-containing powder with an average particle size of 200 μm or less would have been obvious over the active-compound-containing particles taught by Petereit (Page 3, [0056]).

Regarding instant claims 6-7, the anionic analgesic or anionic antirheumatic would have been obvious over the analgesics and antirheumatics, including ibuprofen, taught by Petereit (Page 6, [0094] – [0095]).

Regarding instant claim 11, the limitation of no or only a slight bitter taste for at least 30 seconds after release would have been obvious over the polymer mixture that is particularly advantageous with simultaneously low influence on the tablet disintegration as taught by Petereit. "Even with low polymer applications of 1% by weight, a taste isolation of more than 30 sec is already achieved" (Page 4, [0071]). The limitation of adding the active ingredient powder to a pharmaceutical formulation would have been obvious over the application of the formulation in oral administration forms (Page 6, [0092]).

Conclusion

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615